K001760

AUG 31 2000

SUMMARY OF SAFETY AND EFFECTIVENESS

Sponsor: Biomet Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, IN 46581-0587

Contact Person: Tracy J. Bickel
(219) 372-1761

Device(s): Radiolucent Colles Fracture Kit

Intended Use: Radiolucent Colles Fracture Kit is intended for use in the stabilization of open and/or unstable fractures and where soft tissue injury may preclude the use of other fracture treatments such as IM Rodding, casting and other means of internal fixation.

Classification: Class II. Pin, Fixation, Threaded (888.3040)

Device Description: The Radiolucent Colles Fracture Kit is an external fixator consisting of two pin clamps connected by an 8mm Carbon fiber rod. Each clamp holds two pins that are inserted into the bone on either side of the fracture. The use of a carbon fiber rod will allow the fracture site to be x-rayed from multiple fields without metallic interference. The whole structure is tightened down to eliminate movement at the fracture site. The kit also contains disposable instruments for the insertion and assembly of the fixator.

Potential Risks: The potential risks associated with this device are the same as with any joint replacement device. These include, but are not limited to:

Blood vessel damage	Bone fracture	Infection
Soft tissue imbalance	Metal sensitivity	Nerve damage
Delayed wound healing	Excessive wear	Tissue growth failure
Implant loosening/migration	Fracture of the components	Non-union or delayed union

Substantial Equivalence: The predicate device(s) for this submission include:

- Mini-Fixator by Biomet, Inc.
- Hoffman II by Howmedica
- Monotube by Howmedica
- Dynafix Dimension by EBI
- Mini External Fixation by Synthes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2000

Ms. Tracey J. Bickel
Regulatory Specialist
Biomet, Inc.
56 East Bell
P.O. Box 587
Warsaw, Indiana 46582

Re: K001760
Trade Name: RadioLucent Colles Fracture Kit
Regulatory Class: II
Product Code: LXT
Dated: June 8, 2000
Received: June 9, 2000

Dear Ms. Bickel:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001760
Device Name: Radiolucent Colles Fracture Kit
Indications for Use:

Stabilization of open and/or unstable fractures and where soft tissue injury may preclude the use of other fracture treatments such as IM Rodding, casting, and other means of internal fixation.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Diane R. Vochmer
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001760